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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,816	01/23/2001	Suzy Charbit	H7708-002	1320

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I.P. Docketing
PATERSON, BELKNAP, WEBB & TYLER
1133 Avenue to the Americas
New York, NY 10036

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/768,816

Applicant(s)

CHARBIT ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed December 18, 2006 have been entered. No claims were amended.

Claims 1-23 are pending.

Claims 15-23 stand withdrawn.

Objections

The amendment filed April 18, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "pulmonary fibrosis".

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to arguments

Applicant's arguments filed December 18, 2006 averring one of ordinary skill in the art would realize pulmonary fibrosis are within the scope of the inflammatory and autoimmune disease have been considered, but are not found persuasive. Examiner notes that although *ipsis verbis* is not required for fulfilling the written description requirements, there has to be some blaze marks disclosed in the specification that lead one of skilled in the art to the specific limitations. In the instant case, even though pulmonary fibrosis may be one of the disorders encompassed by the genus of diseases, there is no "blaze marks" provided that leads to the one of skilled in the art that the applicant have possession of treating the underlying cause of "pulmonary fibrosis". The

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instant specification merely discloses the genus and a few specific species other than the specific specie "pulmonary fibrosis".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "underlying cause of ..." recited in claim 1 and 11 renders the claims indefinite as to what underlying causes the claims are encompassed. It is not clear what underlying cause the claims are intended to encompass. Examiner notes that the underlying cause of the disorders is not necessarily elevated IL-1 and TNF- α level since the said disorders or diseased is not necessarily caused or induced by elevated IL-1 and/or TNF- α level. Furthermore, it is not even clear what pathological conditions might be encompassed by the instant claims other than the specific disease states recited in claim 3.

Response to arguments

Applicant's arguments filed December 18, 2006 averring the skilled artisan would understand what pathological conditions being encompassed by the claims have been considered, but are not found persuasive. It is not clear how the disclosure in page 4 of the instant specification define the metes and bounds of the claims. There is no

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description or teachings in the particular passage pointing one of ordinary skill in the art to recognize the recited term "underlying cause of" various diseases might be.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,578,452 ('452) as evidenced by US 5,986,129 ('129).

'452 teaches a method of treating rheumatoid arthritis and oseteoarthritis employing diacerhein (1,8-diacylrhein as taught in '129), in a dosage of 50mg (See page 4, lines 25-38). '452 also teaches diacerhein can be formulated into different dosage forms such as tablet, pill, or a capsule (See page 4, line 1).

The treatment of the underlying cause is considered inherently present in the method of treating rheumatoid arthritis disclosed in '452 since '452 teaches the exact same active method steps as recited. Accordingly, the inhibition of IL-1 and TNF- α levels is also considered inherently present in the method of treating rheumatoid arthritis disclosed in '452.

Response to Arguments

Applicant's arguments filed December 18, 2006 averring the cited prior arts not teaching every recited limitations have been considered, but are not found persuasive.

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Examiner notes that '452 clearly teaches diacerhein as useful to treat the inflammation that causes arthritis. Inflammation is the underlying course of the degradation of the joint (arthritis).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



San-ming Hui
Primary Examiner
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